Remarks

We turn first to the paragraphs 2 – 7 of the detailed action.

Three computer discs constituting the computer readable form of the sequence listing were filed 28 August. All were the same. Objection is made in the current Office Action because the discs are not in ASCII format. Objection is made to the discs not being referenced in the specification.

In response a properly labeled superseding computer readable form of the sequence listing is submitted herewith and also a paper sequence listing corresponding thereto is submitted herewith. The specification is amended herewith to request entering the computer readable form. A Verification Summary Report relating to the computer readable form is submitted herewith indicating no errors. Submitted herewith are statements under 37 C.F.R. 1.821(f) and 1.821(g).

The undersigned is of the opinion that this is a full reply to said paragraphs 2 – 7 to the extent they are in context here.

We turn now to the claims.

There is now only one claim in the case, new claim 17. The other claims are canceled. Basis for new claim 17 is submitted to be found in claims 1-8 and 13-16 and in Figures 3, 4, 7, 8, 9, 10, 11, 12, 13 and 14.

The claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as not being enabled because there is no evidence that triplex structures will form or will have an effect on gene expression, relying on the Wand's factor. The Office Action admits that

the specification provides guidance to identify connectron symmetries in genome sequences (page 4, detailed action).

Before discussion of the rejection is presented, a discussion of the technology is presented. A connectron is a four sequence relationship between two adjacent sequences that are produced as RNA when a gene or a non-coding element transcribes and two non-adjacent sequences which are double stranded DNA. Note that the connectrons are the four sequence relationships and not the triplex structures mentioned in the rejection. The invention involves detecting by computer these relationships in a genome or by computer designing these relationships into a genome. The claimed invention involves pairs of connectrons that cooperate (same length, i.e. number of bases, and same life) or compete (different length, i.e. number of bases, and different lives) and/or which are symmetric (both connectrons have the same sequences) or asymmetric (the two connectrons have different sequences and/or are both dominant or anti-dominant or where one is dominant and the other is anti-dominant). Symmetric and asymmetric connectron pairs are shown in Figures 3 and 4. Competitive blocking of symmetric connectrons is depicted in Figure 11. Competitive blocking of asymmetric connectrons is depicted in Figure 12. Noncompetitive blocking is shown in Figure 14. Cases where (1) both connectrons are dominant or anti-dominant or (2) where one is dominant and the other is anti-dominant, are shown in Figures 7-10.

The invention is directed to, by computer, identifying or designing connectrons that compete/cooperate, and/or are symmetric or asymmetric, and/or are both

dominant, both anti-dominant or where one is dominant and the other is anti-dominant.

Results assuming triplex formation are: that competitive connectrons provide longer lived effect and symmetric/asymmetric and both dominant or anti-dominant and one dominant and the other anti-dominant, provide different biologies.

The Office Action admits that specification provides guidance on "identifying connectron symmetries." There is no reason therefore that the specification does not provide guidance on identifying and designing connectron symmetries. Identification provides guidance to allow designing. The Office Action does not take a contrary position.

We turn now to the lack of enablement rejection, that is the rejection of the claims under 35 U.S.C. 112, first paragraph. Reconsideration is requested. The contention is that there is no enablement because the application does not provide evidence that triplex structures form and have an effect on gene expression.

Firstly it is submitted that the acts of identifying and designing are related to discovery and that is all that is required for enablement. No one would contend that the act of using a microscope for discovery purposes doesn't constitute an enabled use or that modification of what is discovered does not constitute further discovery. It is submitted that in the same way the discovery of claims 1 and 2 is an enabled use per se.

As indicated above, the PTO is contending that something further is required, namely proof that triplex structures will form and have an effect on gene expression. The undersigned disagrees as indicated above.

But even if relying on identification/discovery alone is not sufficient, the PTO position is defective because the law is that applicant does not have to prove that triplex formation occurs within cells and has an effect on gene expression. Rather the burden of proof is on the PTO to prove that discovered four-sequence relationships will not result in triplex formation and have an effect on genome behavior. Casting doubt is not even enough. See Ex parte Reese, 40 U.S.P.Q.2d 1221 (Pat. Off. Bd. App. Int. 1996); In re Dinh-Hguyen, 181 U.S.P.Q. 46,47 (C.C.P.A. 1974) and In re Gardiner, 177 U.S.P.Q. 396, 397 (C.C.P.A.). The PTO has not met this burden.

Moreover pro forma application of the Wands factors as carried out here does not cause the burden of the PTO to change to Applicant. No case says that such does.

The Wands factors are directed to showing lack of enablement in the facts of Wands as described in In re Wands, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988). Consider also Ex Parte Forman, 230 U.S.P.Q. 546,547 (Bd. App. and int. 1986) relied on by Wands for the Wands factor.

The specific issue in Wands involved whether monoclonal antibodies necessary to practice the immunoassay method claimed were enabled without undue experimentation when practice involved screening negative hybridomas to find those that produced the desired antibodies.

In Foreman a question was whether mutant strains of S. typhis necessary for an oral vaccine were enabled when there was a lack of guidance leading to predictable results for obtaining mutant S. typhis.

The instant case differs from Wands and Foreman because no issue has been

raised about treating agents or treating regimen. Thus the specific issues present in Wands and Foreman are not present here.

The issue according to Wand and Foreman is whether the application here describes how to computer mediate identification of sequence listing of connectrons and modification thereof. There is no contention that it does not.

Allowance is requested.

Enclosed is a request for continued examination to assure consideration and entry of the amendment.

Respectfully submitted,
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